

Applicant: Donovan
Serial No.: 09/810,601
Filed: March 15, 2001
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In the Drawings:

H.R. Please replace Fig. 1 with Fig. 1 as enclosed herewith. A version of Fig. 1 with changes shown in red is also enclosed.

Remarks

This is in response to the Examiner's communication mailed November 29, 2002. A response is due December 29, 2002. Accordingly, this response is being timely filed.

The Office Action states that the specification and drawings include amino acid and nucleic acid sequences that are not identified in the Sequence Listing.

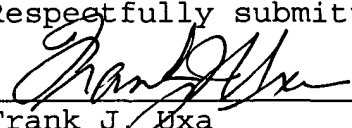
Applicant has reviewed the specification and drawings, and has amended the specification and drawings to recite the proper Sequence Identifiers (SEQ ID NO:).

Applicant has also revised the Sequence Listing to include the sequences that were identified in the specification and drawings, but were not included with the original Sequence Listing. A computer readable form (CRF) copy and a paper copy of the Sequence Listing are enclosed herewith. Also enclosed is a statement that the content of the paper and the computer readable copies are the same and include no new matter. A copy of the Notice to Comply is also enclosed.

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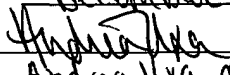
In conclusion, applicant submits that the application is in proper form, and requests a favorable action on the merits.

Date: December 23, 2002

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202, on : December 23, 2002


Andrea Uxa, assistant

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

The paragraph beginning at page 23, line 13 has been amended as follows:

pyroGlu-His-Trp-Ser-Tyr-X-Leu-Arg-Pro-Z (SEQ ID NO: 46)

The paragraph beginning at page 28, line 17 has been amended as follows:

pyroGlu-His-Trp-Ser-Tyr-X-Leu-Arg-Pro-Z (SEQ ID NO: 46)

The paragraph beginning at page 28, line 28 has been amended as follows:

PyroGlu-His-Trp-Ser-Tyr-D-Lys-Leu-Arg-Pro-ethylamide (SEQ ID NO: 9)

The paragraph beginning at page 39, line 8 has been amended as follows:

To reduce the risk of unintentional activation of the toxin by human or commonly encountered proteases, the amino acid sequences of the cleavage site are preferably designed to have a high degree of specificity to proteolytic enzymes which do not normally occur in humans (as either human proteases or occurring in part of the foreseeable human fauna and flora). A non-exclusive list of examples of such proteases includes bovine

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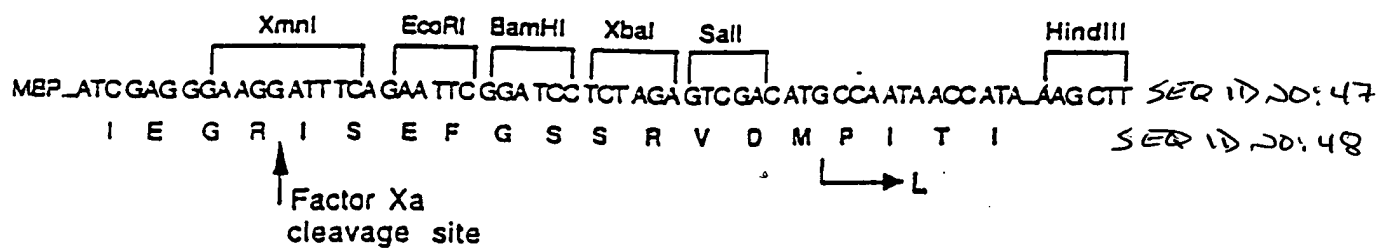
enterokinase, which cleaves the amino acid sequence DDDDK (SEQ ID NO: 50); tobacco etch virus (TEV) protease, which cleaves the sequence EXXYXQS/G (SEQ ID NO: 51); GENENASE® from *Bacillus amyloliquefaciens*, which cleaves the sequence HY or YH; and PRESCISSION® protease from human rhinovirus 3C, which cleaves the amino acid sequence LEVLFQGP (SEQ ID NO: 52). As used above, the letter X indicates any amino acid. All amino acid sequences shown in the present specification are in the direction from amino terminus to carboxyl terminus, and all nucleotide sequences from 5' to 3', (from left to right) unless otherwise indicated.

In the Drawings:

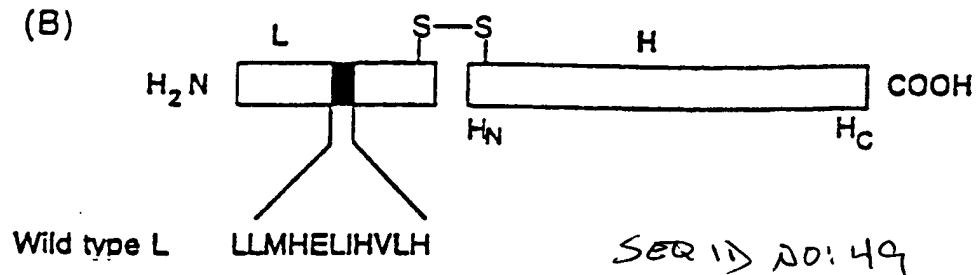
Fig. 1 has been replaced with the enclosed Fig. 1. Fig 1 now identifies the sequences depicted therein.

FIG. 1

(A)



(B)



Application N .: 09/810,601**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Applicant must file the items indicated below within the time period set forth in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: Amino acid sequences cited in Figure 1 and page 39 (lines 17, 18 and 21) of the specification, however, no "SEQ ID NO:" for these sequences are provided in the sequence listing.

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g).

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
- For CRF Submission Help, call (703) 308-4212
- For PatentIn software Program Support:
 - HELP DESK: (703) 739-8559, ext 508, M-F, 8 AM to 5 PM EST except holidays
 - Email: PATIN21HELP@uspto.gov
 - To purchase PatentIn software: (703) 306-2600

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